

Serial No. 09/870,009  
Docket No. JP920000069US1

6

**REMARKS**

Entry of this Amendment if proper because it narrows the issues on appeal and does not require further search by the Examiner.

Claims 5, 8-12 and 15-27 are all the claims presently pending in the application. Claims 5, 8, 11-12, 15-16, 23-24 and 27 have been amended to more clearly define the invention. Claims 5, 8, 11-12 and 15 are independent.

It is noted that the claim amendments are made only for more particularly pointing out the invention, and not for distinguishing the invention over the prior art, narrowing the claims or for any statutory requirements of patentability. Further, Applicant specifically states that no amendment to any claim herein should be construed as a disclaimer of any interest in or right to an equivalent of any element or feature of the amended claim.

Claims 5, 8-12 and 15-27 stand rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. Claim 27 stands rejected upon informalities (e.g., 35 U.S.C. § 112, first paragraph) and claims 17 and 24 stand rejected upon informalities (e.g., 35 U.S.C. § 112, second paragraph).

Claims 5, 8-12, 15-21 and 24-26 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Oliver et al. (U.S. Patent No. 5,723,765).

These rejections are respectfully traversed in the following discussion.

**I. THE CLAIMED INVENTION**

The claimed invention (e.g., as recited in claim 5) is directed to DNA to which information is added. The DNA includes a gene portion including genetic information, a portion, other than the gene portion, including no genetic information, and a nucleotide sequence which is added to the portion including no genetic information, and includes source identification information for identifying a source of the genetic information in the gene portion. Importantly, the nucleotide sequence is added so as not to affect transmission of the genetic information.

Conventional DNA does not include any information therein to determine the source of genetic information (e.g., a value-added gene). Since DNA having such a value-added gene is easily copied, it is difficult to apply technical restrictions to the copying, by third

Serial No. 09/870,009  
Docket No. JP920000069US1

7

parties, of value-added genes.

The claimed invention, on the other hand, includes a nucleotide sequence which is added to a portion of the DNA which includes no genetic information, and which includes source identification information for identifying a source of the genetic information in the gene portion. Importantly, the nucleotide sequence is added so as not to affect transmission of the genetic information. This nucleotide sequence may be used to identify the source of genetic information, for example, when the DNA is copied by a third party. Therefore, the claimed invention helps to prevent illegal copying of such genetic information (e.g., a value-added gene).

## II. THE 35 USC §101 REJECTION

The Examiner alleges that the claimed invention, as recited in claims 5 and 8-12, is directed to non-statutory subject matter. However, Applicant submits that the subject matter of these claims is patentable.

The Examiner attempts to rely on the holding of *Diamond v. Chakrabarty*, 47 U.S. 303, 206 USPQ 193 (1980) to support her allegations. However, the Examiner's reliance is misplaced.

Specifically, as noted at MPEP §2105, the Court in *Chakrabarty* held that microorganisms produced by genetic engineering are not excluded from patent protection by 35 U. S. C. §101. Indeed, the Court held that the test for patentable subject matter in this area is whether the living matter is the result of human intervention. Specifically, the Court held that a "naturally occurring manufacture or composition of matter - a product of human ingenuity - having distinctive name, character, [and] use" is patentable subject matter (MPEP §2105, citing *Chakrabarty*).

The Examiner states that "[i]t is reasonable to interpret the source identification information as a naturally occurring fragment as well as one designed by the hands of man". However, the Examiner erroneously interprets the claims are merely reciting "source identification information" in a portion of DNA. In fact, the claims include recitations which make it clear that the claimed DNA involves some human intervention, and is not "naturally-occurring".

Serial No. 09/870,009  
Docket No. JP920000069US1

8

For example, claim 5 is directed to DNA "*to which information is added*", and further recites "*a nucleotide sequence which is added to said portion including no genetic information, and comprises source identification information for identifying a source of said genetic information in said gene portion, said nucleotide sequence being added so as not to affect transmission of said genetic information*". Applicant points out to the Examiner that claim 5 states that the nucleotide sequence is "added to" a portion of the inventive DNA. This recitation necessarily implies some human intervention.

Indeed, Applicant notes that adding a nucleotide sequence to a portion of DNA is a very complex procedure. Applicant respectfully submits that while the claims do not recite "added by a human", common sense dictates that human intervention is required to add the nucleotide sequence to a portion of DNA. Therefore, the claimed DNA to which a nucleotide sequence has been added inherently requires human intervention and is by definition not "naturally-occurring". Therefore, Applicant respectfully submits that the Examiner's allegations that the claims are directed to non-statutory subject matter are nonsense.

Further, Applicant reminds the Examiner that the words in a claim must be given their plain meaning and must be read as they would be interpreted by those of ordinary skill in the art (MPEP §2111.01, citing *In re Sneed*, 710 F.2d 1544, 218 USPQ 385 (Fed. Cir. 1983) (emphasis added). In addition, while the claims should be examined based on their broadest reasonable interpretation, such interpretation must also be consistent with the interpretation that one or ordinary skill in the art would reach (MPEP §2111, citing *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ 2d 1464, 1468 (Fed. Cir. 1999)(emphasis added)).

Applicant respectfully submits that one of ordinary skill in the art would likely interpret the claims of the present Application to include a nucleotide sequence which is "added" to a portion of DNA with some human intervention. That is, one of ordinary skill in the art would likely not interpret the claims as covering any naturally-occurring DNA. Indeed, this is dictated by common sense.

In summary, the Examiner's allegation that DNA to which a nucleotide sequence (which includes information for identifying a source of genetic information) has been added is naturally-occurring is contrary to common sense and is obviously incorrect. Indeed, the claims are directed to DNA which is a "nonnaturally occurring ... composition of matter - a

Serial No. 09/870,009  
Docket No. JP920000069US1

9

product of human ingenuity - having a distinctive name, character and use" as required by *Charkrabarty*, and are, therefore, directed to patentable subject matter.

Moreover, Applicant further points out to the Examiner that the nucleotide sequence added to a portion of DNA is not just any old nucleotide sequence to a portion of DNA. In fact, the nucleotide sequence includes source identification information for identifying a source of the genetic information in the gene portion.

Again, Applicant submits that this implies some human intervention. That is, without human intervention the "source" of any genetic information in a gene portion is not an issue. For example, a soybean plant is not aware of the "source" of any genetic information in a gene portion of its DNA. The plant does not care if the source of the genetic information was Monsanto or Dow Chemical. Therefore, even assuming arguendo that a soybean plant could through some bizarre mutation, naturally "add" a nucleotide sequence to a portion of its own DNA, that nucleotide sequence would not likely include "source identification information" since the "source" of any genetic information in a gene portion of the soybean DNA is not important to the soybean plant.

Moreover, the source identification information is "for identifying" a source of the genetic information in the gene portion. Applicant again submits that this implies some human intervention. That is, the source identification information is not likely intended for identifying genetic information by the soybean plant. Indeed, common sense again dictates that some human intervention is required "for identifying" the source of the genetic information.

In view of the foregoing, the Examiner is respectfully requested to withdraw this rejection.

### III. THE 35 USC §112, FIRST PARAGRAPH REJECTION

Claim 27 stands rejected under 35 U.S.C. §112, first paragraph. Applicant respectfully disagrees with the Examiner. However, to speed prosecution, Applicant notes that claim 27 has been amended to address the Examiner's concerns.

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw this rejection.

Serial No. 09/870,009  
Docket No. JP920000069US1

10

#### IV. THE 35 USC §112, SECOND PARAGRAPH REJECTION

Claims 17 and 24 stand rejected under 35 U.S.C. §112, second paragraph. Applicant respectfully disagrees with the Examiner.

Applicant respectfully submits that use of the phrase "one of x, y and z" is common and customary claim language and is perfectly acceptable U. S. practice. Indeed, Applicant would point out to the Examiner that U.S. patents are issued every day with claims containing this common language. Therefore, contrary to the Examiner's allegations, claims 17 and 24 are not clear and not indefinite.

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw this rejection.

#### V. THE OLIVER REFERENCE

The Examiner alleges that Oliver teaches the claimed invention. Applicant submits, however, that there are elements of the claimed invention which are neither taught nor suggested by Oliver.

Oliver discloses a method for making a genetically modified plant. The method includes regenerating a whole plant from a plant cell that has been transfected with DNA sequences including a first gene whose expression results in an altered plant phenotype linked to a transiently active promoter. Oliver also discloses a method for making a genetically modified hybrid plant by hybridizing a first plant regenerated from a plant cell that has been transfected with DNA sequences comprising a first gene whose expression results in an altered plant phenotype linked to a transiently active promoter (Oliver at Abstract).

However, contrary to the Examiner's allegations, Oliver does not teach or suggest a nucleotide sequence which is added "*so as not to affect transmission of said genetic information*" as recited in claims 5 and 12 and similarly recited in claims 8, 11, and 15. As noted above, conventional DNA does not include any information therein to determine the source of a value-added gene. Since DNA having such a value-added gene is easily copied, it is difficult to apply technical restrictions to the copying, by third parties, of such value-added genes (Application at page 1, line 8-page 3, line 8).

Serial No. 09/870,009.  
Docket No. JP920000069US1

11

The claimed invention, on the other hand, includes a nucleotide sequence which is added to a portion of the DNA which includes no genetic information, and which includes source identification information for identifying a source of the genetic information in the gene portion (Application at page 11, lines 1-21; page 16, line 8-page 16; page 20, line 6-page Figure 3). Importantly, the nucleotide sequence is added so as not to affect transmission of the genetic information (Application at page 7, line 22-page 8, line 5). The added nucleotide sequence may be used to identify the source of genetic information, for example, when the DNA is copied by a third party (Application at page 11, lines 9-21).

Clearly, these novel features are not taught or suggested by Oliver. Indeed, as noted above, Oliver teaches a method in which a cell is transfected with a gene whose expression results in an altered plant phenotype operably-linked to a transiently active promoter (Oliver at col. 35, lines 17-18). This is completely different from the claimed invention which includes a nucleotide sequence which is added, not to a gene portion of the DNA, but to a portion including no genetic information.

The Examiner surprisingly interprets "source identification information" to mean "information identifying a particular gene". However, the Examiner misses the point. In the present invention, the source identification information does not necessarily "identify a particular gene" as the Examiner puts it, but identifies the source of the genetic information. Applicant respectfully points out to the Examiner that merely identifying genetic information does not identify the source of the genetic information.

For example, if the DNA includes a value-added gene, merely identifying the value-added gene as "Gene X" does not necessarily identify the source of Gene X. Indeed, Gene X may have many different sources.

The Examiner further attempts to equate the promoter in Oliver with the "nucleotide sequences which include the source identification information of the present invention. However, this is clearly incorrect.

Applicant would respectfully point out to the Examiner that the term "promoter" is defined as one that promotes. In the biotechnology world, a "promoter" refers to a segment of DNA which precedes a gene and controls the gene's activity. Thus, Contrary to the Examiner's allegations, a promoter by definition affects transmission of said genetic

Serial No. 09/870,009  
Docket No. JP920000069US1

12

information.

Further, Applicant respectfully points out that the Examiner has incorrectly identified the claims of the present Application as stating that the nucleotide sequence is added so as not to "affect the regular transmission of genetic information". Applicant suspects that the Examiner has intended this definition to overcome the fact that Oliver discloses a "transiently-active promoter" (e.g., a promoter that is only transiently-active).

In fact, contrary to the Examiner's allegations, the claims of the present invention recite a nucleotide sequence that is added "*so as not to affect transmission of said genetic information*". Therefore, a sequence such as the promoter in Oliver that "transiently" controls a gene, does not teach or suggest the nucleotide sequence of the present invention.

In summary, although the promoter and the gene in Oliver may be "operably-linked", the promoter does not necessarily say something about the source of the "toxic gene" to which the promoter is linked. For example, nowhere does Oliver teach or suggest detecting the promoter and using it to identify the source of the "toxic gene". Indeed, Applicant notes that the purpose of the promoter is to terminate embryogenesis upon the application of external stimulus. In other words, there will eventually be no progeny to copy in Oliver and, therefore, no reason to identify the source of the "toxic gene" to prevent illegal copying by a third party.

Further, an important distinction between the claimed invention and the Oliver method, is whether the gene expression is used as a method of extracting correlated information. The Examiner seems to infer the safety of a "special sequence" from the fact that the promoter becomes active (and the gene is expressed) only transiently. However, the claimed invention does not intend the special sequences to change the function (e.g., the characteristics) of the organism at all. This may be realized by not associating the sequences with any genetic functions. Since the sequence has no meaning genetically, it can be concluded that it is harmless. Indeed, careful tests should be performed to check the safety of the inserted sequence.

Therefore, Applicant submits that there are elements of the claimed invention that are not taught or suggest by Oliver. Therefore, the Examiner is respectfully requested to withdraw this rejection.

Serial No. 09/870,009  
Docket No. JP920000069US1

13

#### VI. FORMAL MATTERS AND CONCLUSION

The Examiner alleges that the Application fails to comply with 37 C. F. R. §§1.821-1.825. Submitted herewith are replacement drawing sheets for Figures 8 and 9 which address the Examiner's concerns. Specifically, the nucleotides included in the sequences other than the watermark sequence and the sequence complementary to the watermark, have been replaced with an "X".

Applicant notes that claim 16 has been amended to address the Examiner's objection thereto.

Re-submitted herewith is an Appointment of Associate Attorney which was originally filed on May 9, 2003.

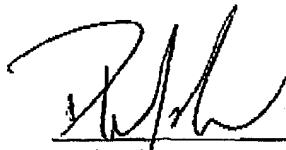
In view of the foregoing, Applicant submits that claims 5, 8-12 and 15-27, all the claims presently pending in the application, are patentably distinct over the prior art of record and are in condition for allowance. The Examiner is respectfully requested to pass the above application to issue at the earliest possible time.

Should the Examiner find the application to be other than in condition for allowance, the Examiner is requested to contact the undersigned at the local telephone number listed below to discuss any other changes deemed necessary in a telephonic or personal interview.

The Commissioner is hereby authorized to charge any deficiency in fees or to credit any overpayment in fees to Assignee's Deposit Account No. 50-0510.

Respectfully Submitted,

Date: 10/14/03



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